REMARKS

In the Office Action dated January 16, 2004, the Examiner has set forth a further requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following inventions:

Group I. Claims 1-49, 61-74, drawn to an isolated nucleic acid comprising a neocentromere or a construct comprising a neocentromere, classified in class 536, subclass 23.1.

Group II. Claims 50-60, drawn to an artificial chromosome for use in gene therapy, which comprises a nucleic acid capable of conferring a phenotypic property on a cell, classified in class 514, subclass 44.

The Examiner contends that Groups I and II are comprised of multiple inventions drawn to different and distinct sequences which do not render each other obvious and thus are patentably distinct. The Examiner states that, if either Group I or II is elected, Applicants must elect a single invention which is the product drawn to one specific sequence to which the claims will be restricted. The Examiner indicates that this restriction to examination of a single sequence is due to the high and undue burden for examining more than one sequence in an application.

In order to be fully responsive to the Restriction Requirement, Applicants provisionally elect, with traverse, the subject matter of Group I, Claims 1-49 and 61-74, drawn to an isolated nucleic acid comprising a neocentromere or a construct comprising a neocentromere. Furthermore, Applicants provisionally elect, with traverse, SEQ ID NO: 3, for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for

restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present case, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. In the first instance, Group I, claims 1-49, 61-74, drawn to an isolated nucleic acid comprising a neocentromere or a construct comprising a neocentromere, are clearly related to Group II, drawn to an artificial chromosome which is a replicating element and segregates with cell division. In fact, the artificial chromosome of Group II is a form of the genetic construct of Group I, as described in the specification, e.g., at page 20, line 16. In addition, the nucleic acid comprising a neocentromere of Group I, uniquely provided by the present application, permits the development of the artificial chromosome of Group II. Clearly, Group I and Group II are not independent and distinct, as the Examiner has allegedly, but are linked to each other as different aspects of a single invention.

Furthermore, nucleic acid molecules comprising a sequence as set forth in SEQ ID NO: 3-29, as presently claimed, are all related to each other as molecules which, when activated, function as a centromere. Specifically, SEQ ID NO: 3 sets forth the sequence of

the HC-contig for human chromosome 10, i.e., the neocentromere located at or around human chromosome 10q25. SEQ ID NO: 4 sets forth the sequence of NC-contig from mardel (10), i.e., the region of chromosome 10 from the patient BE which comprises a neocentromere. SEQ ID NOS: 5-29 set forth the sequences of separate contigs of the p' region (F-2) of mardel (10) neocentromere. It is respectfully submitted that isolated nucleic acid molecules comprising any of SEQ ID NOS: 3-29 are not independent, but are related to each other as different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as

here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present

application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups and sequences, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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